OCT 1 0 2001

510(k) Summary

Introduction

This 510(k) Summary document is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

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USA Submission Correspondent

Robert N. Clark
Medical Device Regulatory Advisors
Golden, Colorado, USA
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

October 4, 2001

Trade Name of Device

Helix Hydro-Jet ®

Common Name of Device

Water Jet Dissector

510(k) Classification

Class II

Indications for Use

The Helix Hydro Jet is intended for cutting and dissection of soft tissue such as liver and kidney in open abdominal surgery.

Comparison to Predicate Devices

The following prior legally marketed devices have been used to establish substantial equivalence:

K982266	HydroCision Arthroscopic Cutting System	HydroCision, Inc.
K991383	HydroCision Inc. Debridement System	HydroCision, Inc.
K993564	Possis AngioJet Xpeedior Catheter	Possis Medical, Inc.
K990430	Ultracision Harmonic Scalpel Hand Piece	Ethicon Endo-Surgery, Inc.

Non-Clinical Testing

The requirements of the following standards have been used in part to establish substantial equivalence:

Biocompatibility Testing:

Biocompatibility testing was successfully completed for patient contact materials, according to the requirements of standard ISO 10993-1.

Safety Testing:

Safety testing was successfully completed on the device according to the requirements of standard EN 60601-1 / IEC 601-1.

EMC Testing:

EMC testing was successfully completed on the device according to the requirements of standard EN 60601-1-2.

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

The device has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in surgical procedures, trained in the use of water jet surgical cutting systems, and must be familiar with all labeling and instructions for use associated with the device.

Andreas Pein Medizintechnik believes that the Helix Hydro-Jet® is safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices for the purposes intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Andreas Pein Medizintechnik GMBH
c/o Mr. Robert N. Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
Golden, Colorado 80401

Re: K012464
Trade/Device Name: Helix Hydro-Jet
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH
Dated: July 30, 2001
Received: August 1, 2001

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MS for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K012464

Device Name: Helix Hydro-Jet

Indications for Use:

The Helix Hydro-Jet is intended for cutting and dissection of soft tissue such as liver and kidney in open abdominal surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012464

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)